

REMARKS

Rejection of Claims 6-7 Under 35 U.S.C. §112, First Paragraph

The Office Action states that claims 6-7 are rejected under §112, first paragraph because “the specification, while being enabling for methods of detecting breast cancer by comparing expression levels of SEQ ID NO: 1...does not reasonably provide enablement for methods of detecting any cancer or pre-malignant condition thereof by comparing expression levels of SEQ ID NO: 1” (emphasis omitted). Applicants traverse the rejection in view of the currently amended claims.

As amended, the instant claims are drawn to a method of detecting colon cancer or a pre-malignant condition thereof by comparing the expression levels of SEQ ID NO: 1. As amended, the scope of the claims has been reduced from a method of detecting any cancer, to a method for detecting colon cancer. The specification provides a working example, teaching that the sequence represented by SEQ ID NO: 1 was identified as being differentially expressed in colon cancer tissue relative to normal colon tissue. Thus, the sequence of SEQ ID NO: 1 is a useful diagnostic marker for the detection of colon cancer; the differential expression of SEQ ID NO: 1 correlates with the presence of colon cancer. Given the teachings in the specification, and the presence of working examples of the differential expression of SEQ ID NO: 1 in colon cancer, one of skill in the art would be able to use the expression level of SEQ ID NO: 1 in a method to detect colon cancer without resorting to under experimentation. No further experimentation is required to practice the claimed method.

The Office Action states that the state of the art indicates that the sequence of SEQ ID NO: 1 is a useful marker for breast cancer detection. Indeed, Su et al. teaches that SEQ ID NO: 1 is differentially expressed in breast cancer. The Office Action states that “there is nothing in the specification that indicates that SEQ ID NO: 1 is specific for any type of cancer.” Applicants respectfully disagree. First, in light of the amendment to the claims, it is irrelevant whether Su et al. teaches that SEQ ID NO: 1 can serve as a marker for breast cancer; the instant claims are drawn to methods for detection of colon cancer. Second, the specification clearly indicates that the

differential expression of SEQ ID NO: 1 is specific for colon cancer. That is, the sequence of SEQ ID NO: 1 was identified to be differentially expressed in colon cancer and is, thus, a specific marker for this type of cancer. The specification teaches that SEQ ID NO: 1 is a diagnostic marker, and teaches how to determine the differential expression of the sequence of SEQ ID NO: 1. Thus, one of skill in the art would be able to practice the full scope of the claimed invention without having to resort to undue experimentation.

The amended claims are fully enabled by the instant specification and Applicants, therefore, request that the rejection be reconsidered and withdrawn.

Rejection of Claims 6-7 Under 35 U.S.C. 102(e)

The Office Action states that claims 6-7 are rejected under §102(e) as anticipated by Su et al. The Office Action states that Su et al. teaches a method for detecting breast cancer in a subject by determining the expression level of SEQ ID NO: 1, comparing the level to control, and basing a diagnosis of breast cancer on the difference in expression levels. Applicants traverse the rejection in view of the currently amended claims.

It is well settled law that to anticipate a claim, a prior art reference must teach, either expressly or inherently, each element of the claimed invention. See, e.g., *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368 (Fed. Cir. 2005).

As amended, the instant claims are drawn to a method for detecting colon cancer or a pre-malignant condition thereof by determining the differential expression of SEQ ID NO: 1. Su et al. does not teach or even suggest that SEQ ID NO: 1 is differentially expressed in colon cancer. Moreover, Su et al. does not teach or even suggest that SEQ ID NO: 1 could be used in a method for the detection of colon cancer. Accordingly, Su et al. does not teach each element of the claimed invention, either expressly or inherently, and therefore does not anticipate the instant claims. Applicants, therefore request that the rejection be reconsidered and withdrawn.

Double Patenting

The Office Action states that claims 6-7 are provisionally rejected under the doctrine of non-statutory obviousness-type double patenting. The Office Action states that claims 6 and 7 are unpatentable in view of the claims of copending applications: 09/328,111; 09/879,536; 09/871,161; and 10/610,049. Applicants disagree and traverse the rejection.

At the outset, Applicants note that applications 09/879,536 and 09/871,161 are abandoned. Thus, the double patenting rejection is moot as to those applications.

With respect to the remaining applications cited in the rejection, the Office Action bases the double patenting rejections on an assertion that the instant claims and those of the cited applications are of "common subject matter" and drawn to "similar methods." Similar subject matter does not provide a sufficient foundation on which to base a double patenting rejection. Moreover, until such time as claims are allowed in either the instant application or the cited applications, this is still a provisional rejection. It is not possible to determine at this time whether a double patenting rejection is appropriate absent a clear picture of the claim scope to be issued in the instant case or the cited applications. Upon notification by the Patent Office of otherwise allowable subject matter in this case or the cited applications, Applicants will consider the relevant scope of the claims in these cases.

As noted in the Office Action, the purpose of the non-statutory obviousness-type double patenting rejection is to prevent the extension of a right to exclude and prevent harassment by multiple assignees. The rejection must be founded in a lack of patentable distinctiveness between the instant claims and those of the cited applications. The Office Action has not provided any indication as to the basis for finding that the instant claims are not patentably distinct over the cited references with respect to the detection of colon cancer or a premalignant condition thereof by determining the expression of SEQ ID NO: 1. Applicants believe that the instant claims are patentably distinct over those in the cited applications, and respectfully request that the rejection be reconsidered and withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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